ATSDR Work Plan for Libby Amphibole: The Libby Community Based Research Initiative (LCBRI)

Introduction and Purpose

Since 1999, the Agency for Toxic Substances and Disease Registry (ATSDR) has worked in collaboration with the United States Environmental Protection Agency (EPA) and a number of other partners in evaluating the public health consequences of community exposures to amphibole asbestos and other similar fibers from Libby, Montana. Vermiculite that contains amphibole asbestos, was mined in Libby and also shipped to over two hundred sites all over the United States. Inhalational exposures occurred among workers, their family members and residents of Libby and in other impacted communities as a result of mining, processing or other handling and use of the contaminated ore and related products and waste materials. The health effects of exposure to asbestos have been well documented previously in occupational and environmental settings. The purpose of this document is to provide the framework for an ATSDR funded Libby Community Based Research Initiative (LCBRI) and other related work. This work will be conducted in close collaboration with EPA and a number of other potential partners and will focus on the epidemiological aspects and assessment of human health impact of these exposures to further address the research and public health needs related to Libby amphibole exposures. In the planning and implementation of this work, ATSDR will focus and prioritize those activities that directly support and complement EPA's Libby Toxicity Assessment Action Plan (LTAAP)[1]. These plans together outline EPA's and ATSDR's ongoing commitment to provide information that will allow the public health community to better understand and manage the adverse health effects associated with exposure to Libby amphibole asbestos.

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Broader Implications for Public Health

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Despite a developing body of scientific knowledge and a significant asbestos related knowledge base, ATSDR and EPA have identified a number of relevant and significant science and data gaps related to these exposures. Addressing these gaps is important to enable scientists, clinicians and policy makers to better prevent and/or manage past, current and future exposures to Libby amphibole.

In addition, the knowledge gained may have significant impact on understanding of similar exposures in other settings such as occupational exposures to similar fibers and

[1] In January 2007, EPA convened a group of more than 30 scientists from EPA, the Agency for Toxic Substances and Disease Registry and the National Toxicology Program to identify data gaps and recommend additional studies to support the baseline human health risk assessment for the Libby, Montana Asbestos site. These recommended studies became the "Libby Toxicity Assessment Action Plan." The Plan is comprehensive program of 12 interrelated project areas designed to ensure that the Superfund program has information it needs to support a baseline risk assessment for the Libby Site and to improve the understanding of the long-term public health effects associated with exposure to Libby amphibole asbestos.

non-commercial asbestos exposures in communities and their related health risks. Regardless of the mechanisms, studies of former workers and residents of Libby have shown that people who were exposed to Libby amphibole-contaminated vermiculite have an increased likelihood of developing asbestos-related health effects, including asbestosis, lung cancer, mesothelioma, and pleural disease.

ATSDR Guiding Principles for Future Research and Public Health Activities

In its Libby related research, ATSDR has utilized several important "guiding principles" for prioritizing projects and allocating resources. In the past, projects that fulfill one or more of these criteria have been considered favorably by the Agency and these will continue to provide guidance and future direction for the Agency.

These principles for future work include the following:

- Protective of public health
- Advance the relevant body of scientific knowledge
- Assist ATSDR and partners in public health decision making and policy-making (e.g. EPA risk assessment)
- Provide information essential for preventing or mitigating exposures
- Serve the needs and concerns of the affected community

ATSDR Priority Focus Areas for Libby Amphibole

Based on assessment of the existing body of knowledge and related science gaps for Libby amphibole related research, ATSDR will complete ongoing work and support future work designed to provide a better understanding of the epidemiology of Libby amphibole related health outcomes. ATSDR proposes to focus its future efforts on specific projects designed to further clarify and address specific knowledge gaps related to the nature and severity of health outcomes, exposure and related health risks.

- **Key specific areas of activity which ATSDR will manage include**:
  - **Epidemiological studies** of persons exposed to Libby asbestos;
    - Health assessment of persons originally exposed to Libby amphibole in childhood.
    - Expanded epidemiological of persons exposed in Libby; to include additional follow-up medical screening, improved exposure questionnaires and use of additional clinical data (e.g. CT scanning, complete pulmonary function test results).
    - Assessment of non-pulmonary health effects of Libby amphibole exposure (e.g. auto-immune conditions).
    - Surveillance of Libby amphibole related health outcomes including development of data systems and local infrastructure to link various existing and available data sets with NIOSH and EPA.

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- Further epidemiologic investigation of the **Marysville, Ohio** cohort; newly obtained worker exposure data may be useful in the development of reference toxicity values (worker study published previously).
- **Dosimetric modeling** and simulation for pulmonary deposition and clearance of fibers. In the future, a valid dosimetry model would allow quantitative prediction of internal dose across species to facilitate improved understanding of the exposure-response relationship in humans.
- Limited update of the **Tremolite Asbestos Registry (TAR)** including review of mortality and cancer incidence.
- Study of **digital vs. plain film chest radiographs** for B reading (currently underway in collaboration with NIOSH).

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Surveillance of Libby amphibole related health outcomes including **development of data systems and local infrastructure** to link various existing and available data sets

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Additional information on cost estimates and timelines is provided in Table 1.

Mechanisms and Respondent Requirements

ATSDR anticipates utilizing a combination of funding mechanisms to conduct the work with a major portion of new work being conducted under a cooperative agreement. Summary of key requirements for the cooperative agreement respondents include:

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- Academic institutions with significant experience and expertise in clinical and public health aspects of asbestos exposure and disease including Libby amphibole
- Substantial "track record" of development and implementation of community based public health research programs with history of relevant publication in peer reviewed literature
- Experience, resources and infrastructure for working closely with the community, state, local and Federal partners and stakeholders in development of a "research and public health agenda"
- Commitment to maintain a long term presence in the Libby community to enhance communication with and between stakeholders, provide management of data and related infrastructure issues and facilitate community based research activities

ATSDR expects that the recipient will establish and operate a "field station" in Libby. The office will be staffed by qualified researchers and support staff as appropriate to conduct and/or coordinate the proposed activities. Close, ongoing collaboration and communication with internal partners at the parent institution and with the community, ATSDR, the United States Environmental Protection Agency (EPA) and other external partners is anticipated and expected. The recipient will provide leadership and support for convening and maintaining a scientific advisory committee for the research effort and a community advisory group to represent the needs of the Libby community. These initiatives must incorporate and/or link with existing efforts for research oversight and community involvement.

ATSDR expects that the research initiative will build upon work already underway in Libby or related to other sites that received Libby vermiculite. Therefore the grantee must also develop mechanisms for continuation of "work in progress" with existing partners.

Summary

Since 1999, ATSDR has been involved in understanding and addressing the public health consequences of exposure to contaminated vermiculite ore from Libby, Montana. This document provides a proposed work plan for ATSDR's ongoing and future efforts and the implementation of a Libby Community Based Research Initiative in support of and complementing EPA's LTAAP activities. In conducting additional future work, ATSDR will continue to build upon its existing expertise in epidemiology, environmental public health and community based research and will seek to build and enhance relationships with key stakeholders and partners to forge an effective public health research agenda for Libby amphibole.

Table 1 (Estimated Project Funding and Timelines for LCBRI)

Activity Description	Estimated Time Line	Estimated Cost 1st Year	Estimated Total Cost ($)	Lead Agency/Comments
Epidemiology studies -Childhood exposure -Expanded epi studies -Non-pulmonary health effects	2-5 years	1,000,000	3,000,000	Recipient TBD
-Ongoing surveillance and data systems	5 years	165,000	825,000	Appropriate local provider*
Marysville Epidemiology	2 years	500,000	1,000,000	TBD
Dosimetric modeling	2 years	150,000	275,000	EPA
Limited update of TAR	2 years	250,000	500,000	ATSDR/State of Montana
B-Reader Study	1 year	200,000	200,000	ATSDR/NIOSH- in progress
Intramural costs (ATSDR)	5 years	180,000	1,200,000	ATSDR
GRAND TOTAL		1,445,000	8,000,000	

* NOTE: In FY 2008, a separate congressional earmark of approximately $250,000 was provided to the Libby Center for Asbestos Related Diseases (CARD) for similar activities

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Ongoing surveillance and data systems	5 years	163,000 per year	815,000*	Appropriate local provider